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First Named Inventor	Sidney Smith
Art Unit	3727
Examiner Name	Jes F. Pascua
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ENCLOSURES *(Check all that apply)*

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THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant(s):	Sidney Smith et al.
Appl. No.:	09/813,351
Conf. No.:	3473
Filed:	March 19, 2001
Title:	LARGE VOLUME FLEXIBLE CONTAINER
Art Unit:	3727
Examiner:	Jes F. Pascua
Docket No.:	CRTS-5679 (0112713-968)

Commissioner for Patents
P.O. Box 1450
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APPEAL BRIEF

Sir:

The Appellants submit this Appeal Brief in support of the Notice of Appeal filed on June 28, 2006. This Appeal Brief is submitted in response to the Final Office Action dated March 29, 2006.

I. REAL PARTIES IN INTEREST

The real parties in interest for the above-identified patent application on appeal are Baxter International Inc., and Hyclone Laboratories, Inc., by virtue of an Assignment recorded at the United States Patent and Trademark Office on September 17, 2001, at reel 012172, frame 0809. Hyclone Laboratories, Inc., is a subsidiary of Fisher Scientific International, Inc.

II. RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' legal representative and the Assignees of the above-identified patent application do not know of any prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

III. STATUS OF CLAIMS

Claims 2, 6-8, 12, 14-15, 17-19, 22-23, 29-31, 36-49, and 51-56 are pending in the above-identified patent application, with claim 17 being the sole independent claim. Claims 1, 3-5, 9-11, 13, 16, 20-21, 24-28, 32-35, and 50 have been canceled. Claims 39-42 and 45-49 have been determined to contain allowable subject matter if rewritten in independent form. A copy of the claims on appeal is included in the Claims Appendix.

IV. STATUS OF AMENDMENTS

A final Office Action was mailed on December 19, 2005. Appellants filed a *Request for Reconsideration* on March 26, 2006. In the *Request for Reconsideration*, Appellant requested that Examiner Pascua consider the *Hurst Affidavit* which accompanied Appellants' Response to Office Action submitted on October 19, 2005. The USPTO identified the *Hurst Affidavit* as an Artifact and therefore did not scan or place the *Hurst Affidavit* into the record. In response to Appellants' *Request for Reconsideration*, Examiner Pascua considered the *Hurst Affidavit* and issued a final Office Action on March 29, 2006. This Appeal Brief is submitted in Response to the March 29, 2006 final Office Action. A copy of the March 29, 2006 final Office Action is attached as Exhibit A.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the claimed subject matter by way of reference to the drawings and specification is provided below.

The present claims are directed to a large volume flexible container for holding at least 200L of fluid. (p. 8 lines 7-14). The container is composed of a flexible polymeric material and includes a plurality of panels joined together to form a polygonal sleeve. (p. 5 lines 4-10). Each panel has a peripheral edge and an end segment extending from the end. A fold line (FL) defines the interface between each panel end and its corresponding end segment. (p. 8 lines 24-30, Figures 5-6). The fold lines at the end of each panel cooperate to define an imaginary plane P at the end of the sleeve. (p. 10 lines 26-30, Figure 4). The end segments are folded and joined to form an end panel. (p. 10 lines 7-10). Each end segment has a tapered edge that extends from the panel peripheral edge. Each panel peripheral edge and the tapered edge of the corresponding end segment form an angle A. The magnitude of angle A for at least one panel and end segment pair is 135.01° to about 138°. (p. 10 lines 17-27, figure 5).

Provision of this particular angle range carries several advantages. Large volume containers of 200L or more may contain liquid weighing over 3000 pounds. (p. 1 lines 25-26). This angle range provides more material in the end panel. (p. 10 lines 22-24). In addition, the angle range of 135.01° to 138° permits the end panels to extend beyond the imaginary plane P when the container is filled. (p. 10 lines 27-30, Figure 4). The present container with the angle A range of 135.01° to 138° advantageously provides a unique end panel configuration that reduces container seam stress caused by the substantial hydraulic forces generated by large fluid volumes within the container. (p. 8 lines 13-14, p. 11 lines 1-4). The end segment configuration of the present container also prevents the transfer of additional stresses to other portions of the container. (p. 11 lines 1-5).

The container may also include hanger connections on a top side thereof (p. 13 lines 15-17, Figures 3,7, and 13), a port closure (p. 17 line 27 through p. 20 line 27, Figures 18-21), and a vent closure (p. 19 lines 17-31, Figure 21).

Although specification citations are given in accordance with 37 C.F.R. § 1.192(c), these reference numerals and citations are merely examples of the support in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms

of the claims are limited to the examples in the specification. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the references numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 2, 6-8, 12, 14-15, 17-19, 22, 28, 30, 31, and 52-55 were rejected under 35 U.S.C. §102(b) for allegedly being anticipated by U.S. Patent No. 5,988,422 to *Vallot*. A copy of *Vallot* is attached as Exhibit B.

2. Claims 2, 6-8, 12, 14-15, 17-19, 22, 23, 30, 31, 36-38, 43-44, and 52-56 were rejected under 35 U.S.C. §103(a) for allegedly being obvious in view of *Vallot*.

3. Claims 29 and 51 were rejected under 35 U.S.C. §103(a) as being obvious over *Vallot* in view of U.S. Patent No. 5,788,121 to Sasaki et al. (*Sasaki*). A copy of *Sasaki* is attached as Exhibit C.

VII. ARGUMENT

A. LEGAL STANDARDS

1. Anticipation under 35 U.S.C. §102

Anticipation is a factual determination that "requires the presence in a single prior art disclosure of each and every element of a claimed invention." *Lewmar Marine, Inc. v. Barient, Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Moreover, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a *single* prior art reference." *Verdegaal Bros. v. Union Oil of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)(emphasis added).

Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. *See, e.g. Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364 (Fed. Cir. 2002). In this regard, a reference disclosing "substantially the same thing" is not enough to anticipate. *Jamesbury Corp. v. Litton Indust. Prod., Inc.*, 756 F.2d 1556, 1560 (Fed. Cir. 1985). A reference must clearly disclose each and every limitation of the claimed invention before anticipation may be found.

Further, anticipation cannot be shown by combining more than one reference to show the elements of the claimed invention. *In re Saunders*, 444 F.2d 599 (C.C.P.A. 1971). All elements of a claimed invention must be disclosed in one, solitary reference. As such, it is clear that a reference cannot be utilized to render a claimed invention anticipated without identical disclosure.

2. Obviousness under 35 U.S.C. §103

The Federal Circuit has held that the legal determination of an obviousness rejection under 35 U.S.C. § 103 is:

> whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made...The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art...Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness...Thus, each obviousness determination rests on its own facts.

In re Mayne, 41 U.S.P.Q.2d 1451, 1453 (Fed. Cir. 1997). In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome "by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings." *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). "If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference or references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *In re Fine*, 837 F.2d 1071, 5, U.S.P.Q.2d 1596 (Fed. Cir. 1988). Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Finally, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q., 580 (CCPA 1974).

Further, it is improper to use an invention as a template for its own reconstruction based on hindsight knowledge of the patented invention when the prior art does not contain or suggest that knowledge. *Sensonics, Inc. v. Aerosonic Corp.*, 38 U.S.P.Q.2d 1551, 1554 (Fed. Cir. 1996). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention" *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). In this regard, the invention "must be viewed not after the blueprint has been drawn by the inventor, but

as it would have been perceived in the state of the art that existed at the time the invention was made." *Id.* As such, the Federal Circuit has acknowledged the need for "rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." *In re Dembiczak*, 50 U.S.P.Q. 2d 1614, 1617 (Fed. Cir. 1999).

Moreover, the Federal Circuit has held that the "obvious to try" is not the proper standard under 35 U.S.C. §103. *Ex parte Goldgaber*, 41 U.S.P.Q.2d 1172, 1177 (Fed. Cir. 1996). "An-obvious-to-try situation exists when a general disclosure may pique the scientist curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued." *In re Eli Lilly and Co.*, 14 U.S.P.Q.2d 1741, 1743 (Fed. Cir. 1990).

Of course, references must be considered as a whole and those portions teaching against or away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). "A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant." *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

B. THE REJECTION OF CLAIMS 2, 6-8, 12, 14-15, 17-19, 22, 23, 30, 31, 36-38, 43-44, AND 52-56 UNDER 35 U.S.C. §102(b) SHOULD BE REVERSED BECAUSE *VALLOT* DOES NOT ANTICIPATE OR RENDER OBVIOUS THESE CLAIMS

Claims 2, 6-8, 12, 14-15, 17-19, 22, 28, 30, 31, and 52-55 were rejected under 35 U.S.C. §102(b) for allegedly being anticipated by *Vallot*. Claims 2, 6-8, 12, 14-15, 17-19, 22, 23, 30, 31, 36-38, 43-44, and 52-56 were rejected under 35 U.S.C. §103(a) for allegedly being obvious in view of *Vallot*. Applicants respectfully submit that the anticipation and obviousness rejections based on *Vallot* are improper and based on a misinterpretation of the present claims, a mischaracterization of *Vallot*, and a misapplication of the patent law.

1. Vallot Does Not Disclose Each and Every Claim Element

Independent claim 17 recites, in part, a large volume flexible container with an angle formed between at least one panel peripheral edge and a corresponding end segment tapered edge that is from 135.01° to about 138° to form at least one end segment with 1) "an additional amount of material" 2) permitting the end panel "to extend outwardly...beyond the imaginary plane when the container is filled."

It is a well settled axiom of patent law that every word in a claim must be considered in judging patentability of the claim. *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995); *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Thus, when claim 1 is properly interpreted, it is clear that *Vallot* does not anticipate the present claims as *Vallot* fails to disclose a container having an end segment with 1) "an additional amount of material" permitting 2) the end panel "***to extend outwardly...beyond the imaginary plane*** when the container is filled" as recited in independent claim 17. To the contrary, *Vallot* discloses a sachet having a parallelepiped shape when filled. *Vallot*, abstract, col. 3 lines 9-15. One of ordinary skill in the art would acknowledge that a parallelepiped sachet is a container with six faces, each face being parallel to the opposite face. Accordingly, *Vallot's* container, "***by definition***" includes a bottom face and a top face with weld crossings, the top and bottom faces being "***parallel to each other.***" *Vallot,* col. 3 lines 12-15 (emphases added). Thus, "by definition," *Vallot's* parallelepiped container does not and can not include an end segment that extends beyond the imaginary plane as this would yield a container with non-parallel top and bottom faces. Moreover, one of ordinary skill in the art would readily recognize that an end panel that extends beyond the imaginary plane would result in a container with non-parallel top and bottom faces—in other words, a non-parallelepiped container. *See Smith Affidavit* ¶7 (attached as Exhibit D); *Hurst Affidavit*, ¶11 (attached as Exhibit E). When every word of claim 17 is properly considered, it is clear that *Vallot's* parallelepiped sachet fails to disclose or suggest a container having an end panel that extends beyond the imaginary plane as recited in claim 17.

2. Vallot Does Not Inherently Disclose An End Panel That Extends Beyond the Imaginary Plane

By definition, *Vallot's* parallelepiped container cannot entail an end panel that extends "outwardly...beyond the imaginary plane when the container is filled" as recited in the present claims. The Examiner attempts to fill this deficiency of *Vallot* with the contention that *Vallot's* angle range of 30°-60° inherently discloses end panels "capable of" extending beyond the imaginary plane. *See* Office Action dated March 29, 2006 at ¶3 (attached as Exhibit A) *see also Vallot*, col. 3 lines 9-11, col. 4 lines 33-37, col. 5 lines 53-55. The case law is clear, however, that inherency may not be established by probabilities or possibilities. The mere possibility that *Vallot's* container end panel ***may be capable of*** extending beyond the imaginary plane is not sufficient to constitute anticipation. Rather, inherency requires an evidential showing that the missing descriptive matter (*i.e.*, the extended end panel) is described in the reference, and that it would be so recognized by persons of ordinary skill. *In re Robertson,* 49 USPQ2d 1949 (Fed. Cir. 1999).

Vallot provides no evidential showing, disclosure, or suggestion of a container having an end panel extending beyond the imaginary plane. When *Vallot* is properly read in its entirety, it is clear that the 30°-60° angle range upon which the Examiner relies is a process parameter, this angle range directed to welds or cuts which may be made upon the film structure in order to form the parallelepiped-shaped container. In particular, *Vallot* discloses that cuts or welds of 30°-60° are made upon the films to form the parallelepiped container as follows.

> This parallelepiped shape can in particular be obtained by cutting the edges of the film at 30° to 60° and approximately 45° relative to the vertical axis of the sachet.
>
> Sachet top and bottom welds are effected by a set of welding bars situated:...at an angle in the range 30° to 60° relative to the advance movement of the film in order for the sachet deployed in three dimensions to conform ***exactly*** to the geometry of the bottom and sides of a rigid container in which it will be placed ("K" weld).

Vallot, col. 3 lines 9-11, col. 5 lines 47-57, respectively (emphasis added). Thus, the 30°-60° angle is a processing parameter utilized to obtain the parallelepiped-shaped container. Nowhere does *Vallot* disclose or suggest that the sachet is anything other than parallelepiped-shaped. The Examiner's "mere conjecture" that the 30°-60° angle range found in *Vallot* inherently discloses an end panel that extends beyond the imaginary line 1) demonstrates a misinterpretation of *Vallot* and 2) contradicts the patent law.

Moreover, the skilled artisan would recognize that *Vallot's* container does not include an end panel that extends beyond the imaginary plane. Rather, one of ordinary skill in the art would acknowledge that the parallelepiped configuration of *Vallot's* container requires an angle of exactly 135°. *Smith Affidavit* at ¶ 7, *Hurst Affidavit* at ¶ 10. Thus, *Vallot's* parallelepiped container fails to disclose or suggest a container having an end panel that inherently extends beyond the imaginary plane as recited in the present claims.

3. Vallot Fails to Disclose an Angle Range of 135.01° to 138° with Sufficient Specificity

Assuming *arguendo* that *Vallot's* 30°-60° angle range suggests an end panel that extends beyond the imaginary plane (which it does not), *Vallot* fails to disclose the recited angle range of 135.01° to 138° with sufficient specificity. The MPEP is clear that when a reference 1) discloses a broad range that overlaps a claimed range yet 2) fails to provide a specific example within the claimed range, and 3) evidence exists of unexpected results within the claimed narrow range, the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims. MPEP § 2131.03.

a. Vallot Fails to Provide a Single Example Within the Claimed Angle Range of 135.01°-138°

Vallot fails to provide a single example of a container having the claimed angle range of 135.01° to 138°. Rather, *Vallot* is replete with numerous statements directed to a container having an angle of 45° (135°), a container that is a parallelepiped shape when filled, and a container having a bottom face and a top face that are parallel to each other. *Vallot*, abstract, col. 1 line 66 through col. 2 line 5, col. 3 lines 9-15, col. 4 lines 33-38, col. 5 lines 55-60, FIG. 2. These numerous statements clearly indicate to one of ordinary skill in the art that the parallelepiped *Vallot* container has an angle of 45°, with top and bottom faces that are parallel to each other. *Hurst Affidavit*, ¶¶ 9-10; *Smith Affidavit* at ¶¶6-7. Consequently, *Vallot* lacks an example of a container having an angle in the recited range of 135.01° to 138°. As *Vallot* fails to provide a single example of a container within the claimed angle range of 135.01° to 138°, *Vallot* fails to disclose the claimed angle range with sufficient specificity.

In addition, *Vallot's* broad angle range of 30°-60° (120°-150°) results in non-workable containers. A container with an angle of 30° (120°) does not conform to the support container geometry and is unworkable. *See Hurst Affidavit* at ¶¶ 3-9. Similarly, a container with an angle of 60° (150°) also does not conform exactly to the support container geometry and likewise is unusable. *Id.* Thus, the skilled artisan would realize that *Vallot*'s broad angle range of 30°-60° (120°-150°) fails to teach or suggest the narrow angle range of 135.01°-138° particularly in view of the nonworkable containers provided in *Vallot's* broad angle range. *Hurst Affidavit*, ¶ 9.

b. The Claimed Angle Range of 135.01°-138° Yields Unexpected Results

The claimed container with an angle range of 135.01° to 138° yields unexpected results. Applicants have surprisingly and unexpectedly discovered that the angle range of 135.01° to 138° enables the end panels of the claimed flexible container to extend outwardly enabling full support of the flexible container by the support container. Thus, the outwardly extending end panels of the claimed container allow the hydraulic stress upon the flexible container to be transferred to the rigid support container. *Smith Affidavit* at ¶¶ 3-5, *Hurst Affidavit* at ¶ 11. The parallelepiped container of *Vallot* fails to adequately address the problem of full support within the support container as *Vallot's* parallelepiped container is incapable of having end panels that extend beyond the fold line. *Hurst Affidavit* at ¶ 11.

Moreover, Applicants have surprisingly and unexpectedly discovered that the angle range of 135.01° to 138° yields wrinkle-free large volume flexible containers. This angle range permits wrinkle-free filling and draining for the claimed large volume flexible container. *Smith Affidavit* at ¶¶ 4-5, *Hurst Affidavit* at ¶ 11. Wrinkling is deleterious as it prevents proper filling and drainage of the fluid contents into and from the container. *Smith Affidavit* at ¶ 5. Wrinkle-free draining is advantageous as it permits all of the bio-fluid to be removed from the container. *Hurst Affidavit* at ¶ 11. *Vallot* fails to appreciate the problems associated with wrinkling. *Hurst Affidavit* at ¶ 9.

Vallot has no teaching or suggestion directed to a large volume flexible container having the unexpected results of i) rupture resistant end panels and ii) a wrinkle-free container that occur as a result of the angle range of 135.01° to 138° as recited in the present claims. *Vallot* fails to

provide a specific example of a container having an angle within the range of 135.01°-138°. *Vallot's* broad angle range includes nonworkable containers. The claimed container with the angle range of 135.01°-138° demonstrates unexpected results. *Vallot* fails to disclose the angle range of 135.01°-138° with sufficient specifically and is therefore non-anticipatory art in accordance with MPEP §2131.03.

C. THE REJECTION OF CLAIMS 29 AND 51 UNDER 35 U.S.C. §103(A) SHOULD BE REVERSED BECAUSE SASAKI TEACHES AWAY FROM THESE CLAIMS

Sasaki teaches away from the recited 200L container. In contrast, *Sasaki* discloses small volume bags, namely, bags having a volume of 5-20L. *Sasaki*, col. 11 lines 44-47. *Sasaki's* small volume bags teach away from the large volume, 200L container recited in the present claims. Teaching away is a *per se* demonstration of non-obviousness. *In re Dow Chemical Co.*, 837 F.2d 469 (Fed. Cir. 1988). Moreover, the skilled artisan would appreciate that the design requirements for a flexible container for containing at least 200L of fluid are unique when compared to flexible containers for smaller volumes. *See Smith Affidavit* at ¶ 3. In addition, *Sasaki* has no disclosure whatsoever directed to a flexible container having end segments with tapered peripheral edges.

CONCLUSION

Appellants respectfully submit that claims 2, 6-8, 12, 14-15, 17-19, 22, 28, 30, 31, and 52-56 are novel and non-obvious in view of *Vallot*. Appellants further submit that claims 29 and 51 are non-obvious in view of *Vallot* and *Sasaki*.

The Commissioner is hereby authorized to charge the Appeal Brief of $500.00 and any additional fees to Deposit Account number 02-1818. Please indicate Attorney Docket No. 112713-968 on the account statement.

Respectfully submitted,

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BY _____

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VIII. CLAIMS APPENDIX

PENDING CLAIMS ON APPEAL FOR U.S. PATENT APPLICATION SERIAL NO. 09/813,351

Listing of Claims:

Claim 1 (canceled)

Claim 2 (previously presented): The container of claim 17 wherein the panels form a polygonal sleeve.

Claims 3-5 (canceled)

Claim 6 (previously presented): The container of claim 17 wherein the plurality of panels comprises four panels cooperatively forming a sleeve having a generally rectangular cross-section.

Claim 7 (original): The container of claim 6 wherein two opposing panels are gusseted panels.

Claim 8 (original): The container of claim 7 wherein the gusseted panels have a gusset fold.

Claims 9-11 (canceled)

Claim 12 (previously presented): The container of claim 17 wherein the end segments converge to a line.

Claim 13 (canceled)

Claim 14 (previously presented): The container of claim 17 wherein one of the panels has a port.

Claim 15 (previously presented): The container of claim 14 wherein the port has a port closure in sterile communication with the port, the port closure providing sterile access to the container interior.

Claim 16 (canceled)

Claim 17 (previously presented): A flexible container composed of a polymeric material for holding at least 200L of fluid comprising:

a plurality of panels, each panel having a peripheral edge, an end, and an end segment extending from the end, the end segment having a tapered peripheral edge extending from a corresponding peripheral edge and forming an angle therebetween, the plurality of panels joined together along the peripheral edges to form a sleeve, the panels each having a fold line that cooperate to define an imaginary plane at one end of the sleeve;

an end panel composed of the plurality of end segments folded at the fold line and sealed to each other along the tapered peripheral edges, at least one angle having a range from 135.01° to about 138° and forming at least one end segment with an additional amount of material which permits at least a portion of the end panel to extend outwardly from the sleeve beyond the imaginary plane when the container is filled; and

a second end panel formed at another end of the sleeve to form a closed flexible container.

Claim 18 (previously presented): The container of claim 17 wherein the panels each have a second end and a second end segment extending from each second end, each second end segment having a tapered peripheral edge extending from a corresponding peripheral edge and forming an angle therebetween, the panels each having a second fold line that cooperate to define a second imaginary plane at the second end of the sleeve, the second end panel composed of the plurality of the second end segments folded at the fold line and sealed to each other along the tapered peripheral edges, at least a second angle having a range from 135.01° to about 138° and

forming at least one second end segment with an additional amount of material which permits at least a portion of the second end panel to extend outwardly from the sleeve beyond the second imaginary plane when the container is filled.

Claim 19 (previously presented): The container of claim 17 further comprising first and second opposing side panels wherein the first and second opposing panels are folded on top of themselves when the flexible container is in a folded position.

Claim 20-21 (canceled)

Claim 22 (previously presented): The container of claim 17 wherein the at least one angle is in the range from about 135.5° to about 136.5°.

Claim 23 (previously presented): The container of claim 17 wherein the at least one angle is 136°.

Claim 24-28 (canceled)

Claim 29 (previously presented): The flexible container of claim 17, further comprising a plurality of spaced-apart hanger connection locations at a top side of the flexible container, the hanger connection locations positioned inward from an outer edge of the top side.

Claim 30 (previously presented): The flexible container of claim 17, wherein the end panel extending outwardly beyond the imaginary plane is a bottom side of the flexible container.

Claim 31 (previously presented): The flexible container of claim 17, wherein the first end panel extending outwardly beyond the imaginary plane has a generally vertical orientation.

Claims 32-35 (canceled)

Claim 36 (previously presented): The container of claim 15 wherein the port closure further comprises a communication member having an end attached to the port.

Claim 37 (previously presented): The container of claim 36 wherein the communication member has a length of about six feet to about 30 feet.

Claim 38 (previously presented): The container of claim 36 further comprising a stop member attached to a second end of the communication member.

Claim 39 (previously presented): The container of claim 38 wherein the stop member is a gas permeable, sterile barrier.

Claim 40 (previously presented): The container of claim 39 wherein the barrier prevents fluid from passing into the communication member.

Claim 41 (previously presented): The container of claim 38 further comprising a cover member.

Claim 42 (previously presented): The container of claim 41 wherein the cover member covers the stop member and a portion of the second end of the communication member.

Claim 43 (previously presented): The container of claim 15 further comprising a second port and a vent closure in sterile communication with the second port.

Claim 44 (previously presented): The container of claim 43 wherein the vent closure further comprises a vent tube having an end attached to the second port.

Claim 45 (previously presented): The container of claim 44 wherein the vent closure further comprises a vent plug attached to a second end of the vent tube.

Claim 46 (previously presented): The container of claim 45 wherein the vent plug is a gas permeable sterile barrier to the vent tube.

Claim 47 (previously presented): The container of claim 46 wherein the vent plug equalizes the internal and external container pressure.

Claim 48 (previously presented): The container of claim 47 wherein the vent plug permits complete filling of the container.

Claim 49 (previously presented): The container of claim 48 further comprising a vent valve disposed within said vent tube.

Claim 50 (canceled)

Claim 51 (previously presented): The container of claim 17 further comprising a plurality of spaced-apart hanger connectors on a top panel of the plurality of panels, the hanger connectors being located between a center of the top panel and an outer perimeter edge of the top panel.

Claim 52 (previously presented): The container of claim 17 wherein the entire end panel extends beyond the imaginary plane.

Claim 53 (previously presented): The container of claim 18 wherein the entire second end panel extends beyond the second imaginary plane.

Claim 54 (previously presented): The container of claim 18 wherein each end segment has opposing tapered peripheral edges.

Claim 55 (previously presented): The container of claim 18 wherein the at least second angle is in the range from about 135.5° to about 136.5°.

Claim 56 (previously presented): The container of claim 18 wherein the at least second angle is 136°.

IX. EVIDENCE APPENDIX

Office Action dated March 29, 2006 (Exhibit A)

U.S. Patent No. 5,988,422 to Vallot ("*Vallot*") (Exhibit B)

U.S. Patent No. 5,788,121 to Sasaki et al. ("*Sasaki*") (Exhibit C)

Affidavit of Sidney T. Smith Under 37 C.F.R. §1.132 ("*Smith Affidavit*") (Exhibit D)

Affidavit of William S. Hurst Under 37 C.F.R. §1.132 ("*Hurst Affidavit*") (Exhibit E)

EXHIBIT A

GMD

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,351	03/19/2001	Sidney T. Smith	CRTS-5679 (1417A P 450)	3473

7590 03/29/2006

Baxter Healthcare Corporation
Corporate Research & Technical Services
One Baxter Parkway DF3-3E
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EXAMINER
PASCUA, JES F

ART UNIT	PAPER NUMBER
3727	

DATE MAILED: 03/29/2006

DOCKETED

Due: 6-29-06

Please find below and/or attached an Office communication concerning this application or proceeding.

Pat 4/5/06

Office Action Summary	Application No.	Applicant(s)	
	09/813,351	SMITH ET AL.	
	Examiner	Art Unit	
	Jes F. Pascua	3727	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/7/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,6-8,12,14,15,17-19,22,23,29-31,36-49 and 51-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,6-8,12,14,15,17-19,22,23,29-31,36-38,43,44 and 51-56* is/are rejected.

7)☒ Claim(s) *39-42 and 45-49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's remarks filed 03/07/2006 indicate that an Affidavit of William S. Hurst under 37 C.F.R. 1.132 accompanied Applicant's response filed 10/21/2005. The Hurst affidavit was considered by the USPTO as an Artifact and therefore, the Hurst affidavit was not scanned and placed into the record by the USPTO. Consequently, the Examiner did not consider the Artifact and thus did not consider the Hurst affidavit. For the purpose of considering the Hurst affidavit, the finality of the rejection of the last Office action is withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2, 6, 7, 8, 12, 14, 15, 17, 18, 19, 22, 30, 31, 52, 53, 54 and 55 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,988,422 to Vallot (previously cited). See Figs. 1 and 2.

It is brought to applicant's attention that the angle defined between the longitudinal edges 19, 19' and the tapered edges 17, 17', 18, 18' in Fig. 2 of Vallot is shown as being in the range from about 135.01° to about 138°, as claimed. Moreover, applicant's affidavit, filed 03/11/2005, admits that Vallot discloses an "angle range of

120° -150° between the panel peripheral edge and the end segment tapered edge." See paragraph 6 of the 03/11/2005 affidavit. Having met applicant's claimed range of angles in claims 17 and 18, the end panels of Vallot are inherently capable of extending outwardly from the sleeve beyond an imaginary plane when in the unfolded position shown in Fig. 2.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 2, 6, 7, 8, 12, 14, 15, 17, 18, 19, 22, 23, 30, 31, 52, 53, 54, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallot.

Vallot discloses the claimed invention, especially an angle range of 120° -150° between the panel peripheral edge and the end segment tapered edge, which overlaps applicant's claimed angle range of 135.01° to about 138° and specific angle 136°. However, Vallot does not disclose end panels extending outwardly beyond an imaginary place at the ends of the sleeve as a result of an angle range of 135.01° to about 138° and specific angle 136°. Through routine experimentation, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an angle between the panel peripheral edge and the end segment tapered edge in Vallot with an angle range of 135.01° to about 138° or a specific angle 136°, in order to form

the bag with end panels extending outwardly beyond an imaginary place at the ends of the sleeve. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

6. Claims 36, 37, 38, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallot '422.

Vallot '422 discloses the claimed invention, especially all of the materials used to construct the Vallot '422 container and its accessories being "capable of withstanding exposure to radiation and other known sterilization techniques." See column 3, lines 46-50. However, Vallot does not disclose the port closure (i.e. "stopper") in sterile communication with the port (i.e. "chimneys 8"). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stopper of Vallot '422 in sterile communication with the port of the container since it was known in the art to maintain the contents of bio-pharmaceutical containers in a sterile condition.

Regarding claims 43 and 44, the large diameter tube connector 10, small diameter tube connector 11 or 90° elbow connector 13 meet the structure of applicant's "vent closure" to the same degree as claimed.

Regarding claim 37, Vallot '422 discloses the claimed invention except for the communication member (i.e. a tube connecting to large diameter tube connector 10, small diameter tube connector 11 or 90° elbow connector 13) being about 6 ft. to about 30 ft. long. It would have been an obvious matter of design choice to use a 6 ft. to 30 ft.

tube for the communication member of Vallot '422, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

7. Claims 29 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallot '422 and Sasaki et al.

Vallot '422 discloses the claimed device except for the top side of the container having a plurality of spaced-apart hanger connection locations. Sasaki et al. discloses that it is known in the art to provide a plurality of spaced-apart hanger connection locations 14. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the top side of the Vallot '422 container with the plurality of spaced-apart hanger connection locations of Sasaki et al., in order to permit the container to be suspended. Furthermore, the plurality of spaced-apart hanger connection locations 14 of Sasaki et al are shown as being positioned inward from an outer edge of the top side as claimed.

Allowable Subject Matter

8. Claims 39-42 and 45-49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

9. Applicant's arguments filed 03/06/2006 have been fully considered but they are not persuasive.

Applicant's remark that Vallot fails to provide a single example within the claimed angle range of 135.01°-138° does not remove the fact that the range of angles taught by Vallot anticipate applicant's claims. "[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is anticipated' if one of them is in the prior art." Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

The Smith affidavit, filed 10/21/2005 is identical to the Smith affidavit filed 03/11/2005. Smith affidavit has been considered, but not deemed sufficient to rebut the Examiner's *prima facie* case of obviousness based on overlapping ranges. The Smith affidavit fails to show that the particular angle range of 135.01° to about 138° and specific angle 136° are critical by showing that the claimed angle range and specific angle achieve unexpected results relative to the angle range disclosed by Vallot. In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Since applicant has failed to show evidence exists of unexpected results within the claimed narrow range of 135.01°-138°, the broad angle range of 120°-150° in Vallot meets the claimed narrow range with sufficient specificity.

The Smith affidavit admits that below a certain angle, large volume flexible containers are prone to undesirable rupturing and beyond a certain angle, the large

volume flexible containers exhibited undesirable wrinkling within a support container. Since applicant was aware of these two undesirable conditions, another person having ordinary skill in the art of large volume flexible containers would be aware these two undesirable conditions as well. Therefore, through routine experimentation within the claimed angle range of Vallot, a person having ordinary skill in the art would be able to arrive at an optimum range of angles that provide a large volume flexible container that does not rupture or wrinkle within the support container when filled. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The Hurst affidavit filed 10/21/2005 (and resubmitted on 03/07/2006) has been presented to support applicant's argument that Vallot fails to provide an example within the claimed range of 135.01°-138°. According to the Hurst affidavit, only four models of large volume fluid-filled flexible containers where prepared using finite element analysis. The four models appear to represent the high end and low end of the range of angles in Vallot and the high end and low end of the range of angles in applicant's claims. The Hurst affidavit goes to explain the results of each model (e.g. shape of bag and the amount of wrinkling). The affidavit comes to the conclusion that the high end and low end models of the Vallot range of angles produces a shape or wrinkles that are undesirable and the high end and low end of the claimed range of angles provides a usable container with minimal wrinkling. Paragraph 5 of the Hurst affidavit does not precisely discuss how much more a flexible container with a 120° angle is unsupported

compared to a flexible container with a range of 135.01° to about 138°. The Hurst affidavit also does not discuss the acceptable amount of the flexible container can be unsupported and how this acceptable amount was determined. Paragraph 6 of the Hurst affidavit does not precisely discuss how many more wrinkles occur in a flexible container with a 150° angle than a flexible container with a range of 135.01° to about 138°. The Hurst affidavit also does not discuss the acceptable amount of wrinkling a flexible container can have and how this acceptable amount was determined. The testing and results in the Hurst affidavit neither take into account, nor discuss, angles just outside the angle range of 135.01° to about 138°. The absence of such information in the affidavit does not convince the Examiner that the claimed range of 135.01° to about 138° yields an unexpected bag shape with minimal wrinkling.

Like the Smith affidavit, the Hurst affidavit shows that below a certain angle, large volume flexible containers are prone to undesirable rupturing and beyond a certain angle; the large volume flexible containers exhibited undesirable wrinkling within a support container. Since applicant was aware of these two undesirable conditions, another person having ordinary skill in the art of large volume flexible containers would be aware these two undesirable conditions as well. Therefore, through routine experimentation within the claimed angle range of Vallot, a person having ordinary skill in the art would be able to arrive at an optimum range of angles that provide a large volume flexible container that does not rupture or wrinkle within the support container when filled. "[W]here the general conditions of a claim are disclosed in the prior art, it is

not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In response to applicant's argument that Sasaki et al. is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Sasaki et al. discloses the necessity of providing a plurality of spaced-apart hanger connection locations within a flexible bag that is to be contained within a support container.

Applicant's argument that Vallot fails to adequately address the problem of full support within the support container and the problems associated with wrinkling is not indicative of unexpected results. "The failure of the prior art to mention a problem may be due to the fact that in practice the problem is not a serious one or that a large number of satisfactory solutions is readily apparent." See *In re Gershon*, 372 F.2d 535, 152 USPQ 602 (CCPA 1967). "An allegation of solving an unsolved problem in the art is not evidence of non-obvious unless it is shown that widespread efforts of skilled workers having knowledge of the prior art had failed to find a solution to the problem." See *In re Allen*, 139 USPQ 492, 495 (CCPA 1963).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jes F. Pascua whose telephone number is 571-272-4546. The examiner can normally be reached on Mon.-Thurs..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nathan J. Newhouse can be reached on 571-272-4544. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jes F. Pascua
Primary Examiner
Art Unit 3727

JFP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Sidney Smith et al.
Appl. No.:	09/813,351
Conf. No.:	3473
Filed:	March 19, 2001
Title:	LARGE VOLUME FLEXIBLE CONTAINER
Art Unit:	3727
Examiner:	Jes F. Pascua
Docket No.:	CRTS-5679 (0112713-968)

Assistant Commissioner of Patents

Washington, D.C. 20231

AFFIDAVIT OF SIDNEY T. SMITH UNDER 37 C.F.R. § 1.132

Sir:

I, Sidney T. Smith, hereby state as follows:

1. My education is as follows: I have a Bachelor of Science degree in Chemistry and have completed graduate coursework in Chemical and Biomedical Engineering and Biophysical Chemistry. My work experience includes over 20 years in the design and development of flexible container technology for medical applications, biopharmaceutical solutions, and the biosciences. In addition, I have presented numerous articles on flexible barrier container technology at several industry symposiums.

2. I am one of the named inventors of the above-identified patent application and I am therefore familiar with the inventions disclosed therein. I have recently reviewed the claims of the patent application as they are currently pending. A copy of the pending claims is attached hereto at Tab A.

3. One of the problems with conventional flexible containers for containing large volumes of bio-pharmaceutical solutions of at least 200 liters is that hydraulic forces such as fluid stress and shear that occur within the container, particularly during container transport, are significant enough to rupture the container seams. The present invention is directed to a large

volume flexible container with an improved end panel design that significantly strengthens the container making it more resistant to rupture. Accordingly, in part, the claimed invention provides a large volume flexible container having end segments wherein the angle between the tapered edge of the end segment and the panel peripheral edge is between 135.01° to 138°. This angle range enables the container end panels to extend beyond the plane formed by the sleeve ends. This extended end panel configuration enables the hydraulic stress imposed upon the filled flexible container to be transferred to a support container in which the flexible container is placed.

4. Through a series of experiments, I surprisingly and unexpectedly discovered that by forming an angle of 135.01° to 138° between the panel peripheral edge and the end segment tapered edge, I was able to produce a wrinkle-free large volume flexible container with improved strength and improved resistance to rupture. Providing an angle between 135.01° and 138° permits the end panels to extend outwardly beyond the plane defined by the panel sleeve ends when the container is filled. The outwardly extending end panel, or the "pent roof" feature of the container, provides additional material at the end panel apex forming a flexible container with a wetted surface area that equals or exceeds the wetted surface area of the support container. The outwardly extending end panel thereby reduces the amount of hydraulic stress placed upon the filled container by allowing the hydraulic stress to be transferred to the support container. The angle range of 135.01° to 138° further unexpectedly provides a flexible container that does not wrinkle when placed into the support container.

5. When I prepared large volume flexible containers having an angle less than 135.01°, the end panels did not extend beyond the plane formed by the panel sleeve ends. Consequently, the flexible containers carried excessive stress in the seams and could not transfer the stress to the support container. These flexible containers were prone to rupture. The containers I prepared having an angle greater than 138° exhibited wrinkling when placed in the support container. Wrinkling is deleterious as it prevents proper filling and drainage of the fluid contents into and from the flexible container. As a result of my research and experimentation, I have discovered that the angle range of 135.01° to 138° between the tapered edge of the end segment and the panel peripheral edge produces containers for holding at least 200 liters of fluid

with the unexpected advantages of i) rupture resistant end panels and ii) wrinkle-free filling and draining.

6. A reference relied upon by the Patent Office is U.S. Patent No. 5,988,422 to Vallot (*Vallot*). *Vallot* discloses a parallelepiped-shaped sachet for transporting bio-pharmaceutical liquids. The end panels of the *Vallot* container are formed by cutting the edges of the film at a 45° ±15° angle relative to the vertical axis of the sachet. This translates to an angle range of 120°-150° between the panel peripheral edge and the end segment tapered edge. *Vallot*, however, does not provide a single example of a container wherein the angle is greater than 45°. Conversely, *Vallot* states that the welds on the bottom face and the top face of the parallelepiped sachet are parallel. This clearly indicates that the angle is exactly 45°.

7 Moreover, *Vallot* provides no disclosure regarding a container with end panels that extend beyond the plane defined by the panel ends. Provision of a parallelepiped container requires the *Vallot* end panels to be coplanar with the plane defined by the panel ends. Accordingly, *Vallot's* end panels do not extend beyond the plane defined by the panel ends. In addition, *Vallot* discloses that the flexible container "conforms exactly to the geometry" (col. 5 lines 53-56) of the support container in which it is placed. This further demonstrates that the end panels of the *Vallot* container do not extend beyond the plane defined by the panel ends and further indicates that the angle of the *Vallot* container is not greater than 45°. Regardless of the disclosure of an angle range of 45° ± 15°, it is apparent that *Vallot* fails to recognize the need to transfer stress from the flexible container to the support container and subsequently fails to provide a solution to this need. *Vallot* simply discloses a parallelepiped container wherein the angle between the panel peripheral edge and the end segment tapered edge is exactly 135°. As one skilled in the art reviewing *Vallot*, I would not be taught nor would I be led to construct a large volume flexible container with an end panel that outwardly extends beyond the plane defined by the fold line of each panel. Nor would I be led to construct a large volume flexible container with the angle range of 135.01° to 138° between the panel peripheral edge and the end segment tapered edge that permits stresses on the filled flexible container to be transferred to the support container and reinforcing the end panels while simultaneously providing a flexible container that does not wrinkle during filling and draining.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of any patent that may issue from this application.

FURTHER AFFIANT SAYETH NOT:

Sidney T. Smith

7 MARCH 2005

Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Sidney Smith et al.
Appl. No.:	09/813,351
Conf. No.:	3473
Filed:	March 19, 2001
Title:	LARGE VOLUME FLEXIBLE CONTAINER
Art Unit:	3727
Examiner:	Jes F. Pascua
Docket No.:	CRTS-5679 (0112713-968)

Assistant Commissioner of Patents

Washington, D.C. 20231

AFFIDAVIT OF WILLIAM S. HURST UNDER 37 C.F.R. § 1.132

Sir:

I, William S. Hurst, hereby state as follows:

1. I am one of the named inventors of the above-identified patent application and I am therefore familiar with the inventions disclosed therein. I have recently reviewed the claims of the patent application as they are currently pending. A copy of the pending claims is attached hereto at Exhibit 1.

2. The present claims are directed to a large volume flexible container for holding at least 200 L of a bio-fluid. The large volume flexible container is designed to be placed within a rigid support container. The rigid container supports the significant loads imparted by the fluid forces within the flexible container. Unsupported areas of the flexible container are prone to rupture and are undesired. Unsupported areas of the flexible container may occur as a result of a poor fit between the flexible container and the rigid container and wrinkling of the flexible container.

3. A reference relied upon by the Patent Office is U.S. Patent No. 5,988,422 to Vallot (*Vallot*). A copy of the *Vallot* patent is attached hereto at Exhibit 2. I have reviewed the *Vallot* patent. *Vallot* discloses a parallelepiped-shaped sachet for transporting bio-

pharmaceutical fluids. *Vallot* also discloses that a parallelepiped-shaped container may be made by cutting a film at 30°-60° relative to the vertical axes of the film. *Vallot*'s 30°-60° angle range is the same as the 120°-150° angle range between the panel peripheral edge and the end segment tapered edge with respect to the present claim language angle range.

4. I directed the preparation of four models of large volume fluid-filled flexible containers placed in rigid support containers. These models were prepared using finite element analysis. The first model depicts a container having a 120° angle between the panel peripheral edge and the end segment tapered edge and represents *Vallot's* lower angle limit of 30°. Cross sectional views of the first container model are set forth at Tab A. The second model depicts a container having a 150° angle between the panel peripheral edge and the end segment tapered edge and represents *Vallot's* upper angle limit of 60°. Cross sectional views of the second container model are set forth at Tab B. The third model depicts a container having a 135.01° angle between the panel peripheral edge and the end segment tapered edge and represents the lower angle limit of 135.01° for the claimed container. Cross sectional views of the third container model are set forth at Tab C. The fourth model depicts a container having a 138° angle between the panel peripheral edge and the end segment tapered edge and represents the upper angle limit of 138° for the claimed container. Cross sectional views of the fourth container are set forth at Tab D.

5. The first model having a 120° angle (Tab A) fails to provide a usable container. An angle of 120° yields a container having an arcuate bottom portion. This arcuate bottom portion results in a large areas of the flexible container that are unsupported by the support container. These unsupported areas of the container are prone to rupture resulting in a flexible container that is not viable.

6. The second model having a 150° angle (Tab B) also fails to provide a usable container. An angle of 150° produces a container that experiences extreme wrinkling. Wrinkles are harmful as they act to fracture the film and leak when subjected to sustained dynamic loads that occur during shipping. Wrinkles are further undesired because they manifest themselves as fluid dams preventing accurate dispensing, draining, and filling of the flexible container.

7. The third model having a 135.01° angle (Tab C) provides a usable container. As shown at Tab C, this container is fully supported by the rigid support container. Full support is important as it reduces stressing of the flexible container, correspondingly reducing the possibility of leakage. The container with a 135.01° angle was found to be the lower limit with respect to a workable container. An angle less than 135.01° does not enable the end panel to move outward beyond the sleeve end plane. This ability of the end panel to move outward enables the flexible container to be fully supported by the rigid support container.

8. The fourth model having a 138° angle (Tab D) provides a usable container. The container is fully supported by the support container. The container with a 138° degree angle also experiences minimal wrinkling. An angle of 138° was found to be the upper limit with respect to a workable container. An angle greater than 138° yields excessive wrinkling and poses too great a risk of rupture for use.

9. Based on my review of *Vallot*, and our modeling and experimentation, *Vallot* does not disclose a large volume flexible container having an angle range of 135.01° to 138° between the panel peripheral edge and the end segment tapered edge. *Vallot* appears to recognize the need to fully support the sachet with a rigid support container as *Vallot* discloses that the sachet is to conform exactly to the geometry of the rigid support container. However, the broad angle range of 30°-60° (120°-150°) disclosed in *Vallot* contradicts this as sachets conforming to *Vallot's* broad angle range would be unacceptable for use. The first model (Tab A) clearly indicates that a container having *Vallot's* 30° angle (120) would not be acceptable for use. In addition, it is clear that *Vallot* fails to appreciate or recognize the problems associated with wrinkling. This is apparent as the second model (Tab B) depicting a container with a 150° angle experiences excessive wrinkling and would not be acceptable for use. *Vallot* provides no guidance how to overcome the problems of fully supporting the flexible container in combination with wrinkle avoidance.

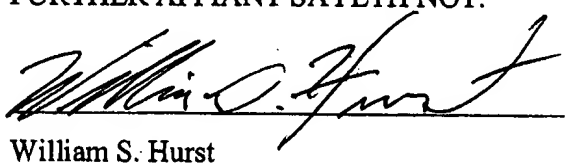
10. At most, *Vallot* discloses a flexible container having a 45° angle, that is a parallelepiped shape, with the top and bottom faces being parallel. *Vallot's* broad angle range

includes unusable containers. Thus, the only concrete example of a workable container in *Vallot* is a container having a 45° (135°) angle. *Vallot* repeatedly describes the container as having a parallelepiped shape and that the top and bottom faces of the container are parallel to each other. This indicates that *Vallot* is only concerned with a container having a 135° (45°) angle between the panel peripheral edge and the end segment tapered edge.

11. Our container having an angle range of 135.01° to 138° as recited in the claims yields unexpected results. The angle range of 135.01° to 138° provides a flexible container that is fully supported by the rigid support container. This angle range permits the end panels to extend outward thereby enabling full support of the flexible container by the support container. A parallelepiped container such as *Vallot's* container having an angle of 45° is incapable of having an end panel that extends beyond the fold line. Our angle range of 135.01°-138° also provides a flexible container with minimal wrinkling. The combination of these features advantageously yields a flexible container that is rupture resistant because it is wrinkle-free and fully supported by the support container and the container is readily drained without leaving bio-fluid within the container.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of any patent that may issue from this application.

FURTHER AFFIANT SAYETH NOT:



William S. Hurst

October 17, 2005

Date

Listing of Claims:

Claim 1 (canceled)

Claim 2 (previously presented): The container of claim 17 wherein the panels form a polygonal sleeve.

Claims 3-5 (canceled)

Claim 6 (previously presented): The container of claim 17 wherein the plurality of panels comprises four panels cooperatively forming a sleeve having a generally rectangular cross-section.

Claim 7 (original): The container of claim 6 wherein two opposing panels are gusseted panels.

Claim 8 (original): The container of claim 7 wherein the gusseted panels have a gusset fold.

Claims 9-11 (canceled)

Claim 12 (previously presented): The container of claim 17 wherein the end segments converge to a line.

Claim 13 (canceled)

Claim 14 (previously presented): The container of claim 17 wherein one of the panels has a port.

Claim 15 (previously presented): The container of claim 14 wherein the port has a port closure in sterile communication with the port, the port closure providing sterile access to the container interior.

Claim 16 (canceled)

Claim 17 (currently amended): A flexible container composed of a polymeric material for holding at least 200L of fluid comprising:

a plurality of panels, each panel having a peripheral edge, an end, and an end segment extending from the end, the end segment having a tapered peripheral edge extending from a corresponding peripheral edge and forming an angle therebetween, the plurality of panels joined together along the peripheral edges to form a sleeve, the panels each having a fold line that cooperate to define an imaginary plane at one end of the sleeve;

an end panel composed of the plurality of end segments folded at the fold line and sealed to each other along the tapered peripheral edges, at least one angle having a range from 135.01° to about 138° and forming at least one end segment with an additional amount of material which permits at least a portion of the end panel to extend outwardly from the sleeve beyond the imaginary plane when the container is filled ~~first end panel is in an unfolded position~~; and

a second end panel formed at another end of the sleeve to form a closed flexible container.

Claim 18 (currently amended): The container of claim 17 wherein the panels each have a second end and a second end segment extending from each second end, each second end segment having a tapered peripheral edge extending from a corresponding peripheral edge and forming an angle therebetween, the panels each having a second fold line that cooperate to define a second imaginary plane at the second end of the sleeve, the second end panel composed of the plurality of the second end segments~~,~~ folded at the fold line and sealed to each other along the tapered peripheral edges, at least a second angle having a range from 135.01° to about 138° and forming at least one second end segment with an additional amount of material which permits at least a portion of the second end panel to extend outwardly from the sleeve beyond the second imaginary plane when the container is filled.

Claim 19 (previously presented): The container of claim 17 further comprising first and second opposing side panels wherein the first and second opposing panels are folded on top of themselves when the flexible container is in a folded position.

Claim 20-21 (canceled)

Claim 22 (previously presented): The container of claim 17 wherein the at least one angle is in the range from about 135.5° to about 136.5°.

Claim 23 (previously presented): The container of claim 17 wherein the at least one angle is 136°.

Claim 24-28 (canceled)

Claim 29 (previously presented): The flexible container of claim 17, further comprising a plurality of spaced-apart hanger connection locations at a top side of the flexible container, the hanger connection locations positioned inward from an outer edge of the top side.

Claim 30 (previously presented): The flexible container of claim 17, wherein the end panel extending outwardly beyond the imaginary plane is a bottom side of the flexible container.

Claim 31 (previously presented): The flexible container of claim 17, wherein the first end panel extending outwardly beyond the imaginary plane has a generally vertical orientation.

Claims 32-35 (canceled)

Claim 36 (previously presented): The container of claim 15 wherein the port closure further comprises a communication member having an end attached to the port.

Claim 37 (previously presented): The container of claim 36 wherein the communication member has a length of about six feet to about 30 feet.

Claim 38 (previously presented): The container of claim 36 further comprising a stop member attached to a second end of the communication member.

Claim 39 (previously presented): The container of claim 38 wherein the stop member is a gas permeable, sterile barrier.

Claim 40 (previously presented): The container of claim 39 wherein the barrier prevents fluid from passing into the communication member.

Claim 41 (previously presented): The container of claim 38 further comprising a cover member.

Claim 42 (previously presented): The container of claim 41 wherein the cover member covers the stop member and a portion of the second end of the communication member.

Claim 43 (previously presented): The container of claim 15 further comprising a second port and a vent closure in sterile communication with the second port.

Claim 44 (previously presented): The container of claim 43 wherein the vent closure further comprises a vent tube having an end attached to the second port.

Claim 45 (previously presented): The container of claim 44 wherein the vent closure further comprises a vent plug attached to a second end of the vent tube.

Claim 46 (previously presented): The container of claim 45 wherein the vent plug is a gas permeable sterile barrier to the vent tube.

Claim 47 (previously presented): The container of claim 46 wherein the vent plug equalizes the internal and external container pressure.

Claim 48 (previously presented): The container of claim 47 wherein the vent plug permits complete filling of the container.

Claim 49 (previously presented): The container of claim 48 further comprising a vent valve disposed within said vent tube.

Claim 50 (canceled)

Claim 51 (previously presented): The container of claim 17 further comprising a plurality of spaced-apart hanger connectors on a top panel of the plurality of panels, the hanger connectors being located between a center of the top panel and an outer perimeter edge of the top panel.

Claim 52 (previously presented): The container of claim 17 wherein the entire end panel extends beyond the imaginary plane.

Claim 53 (previously presented): The container of claim 18 wherein the entire second end panel extends beyond the second imaginary plane.

Claim 54 (previously presented): The container of claim 18 wherein each end segment has opposing tapered peripheral edges.

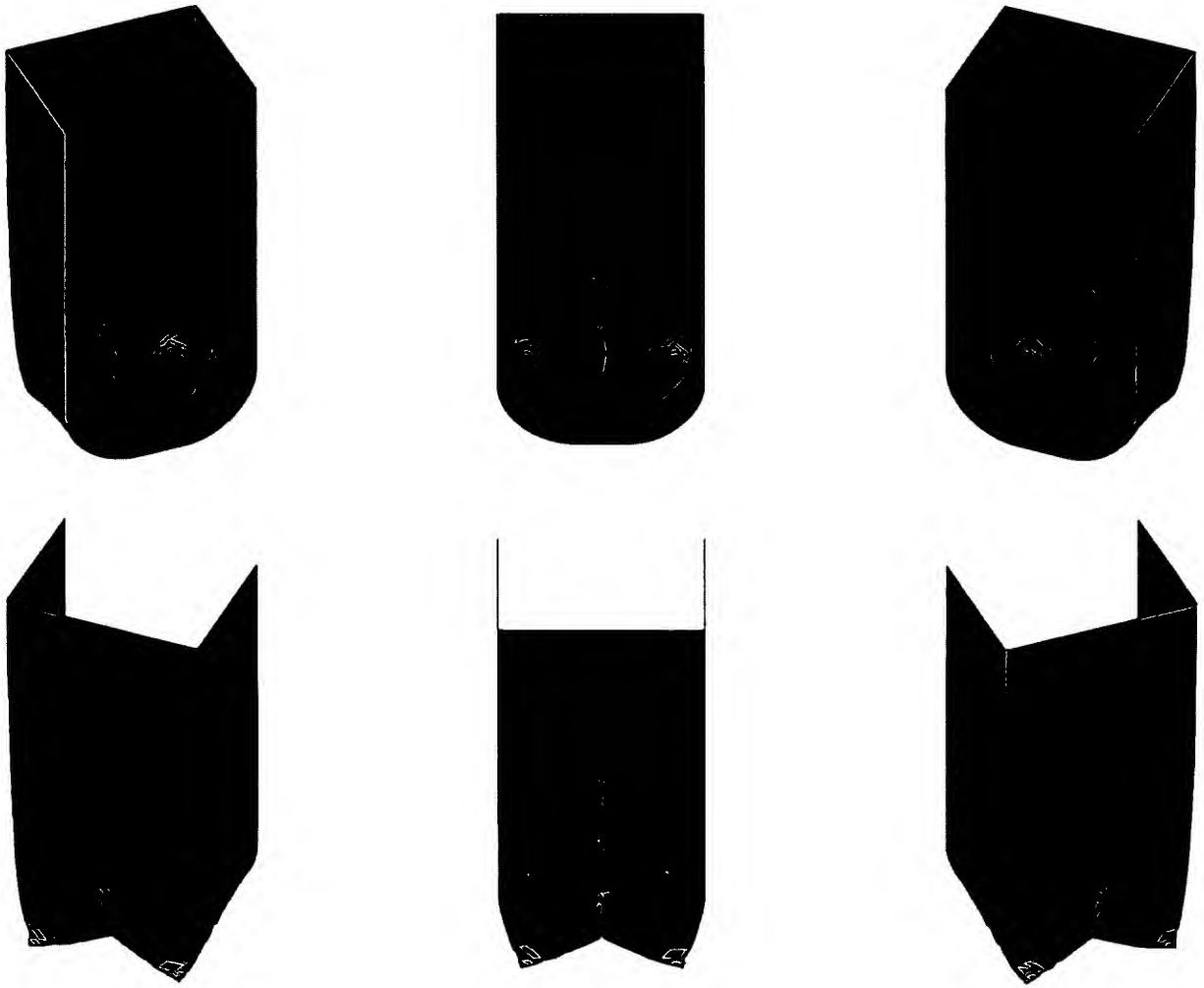
Claim 55 (previously presented): The container of claim 18 wherein the at least second angle is in the range from about 135.5° to about 136.5°.

Claim 56 (previously presented): The container of claim 18 wherein the at least second angle is 136°.

Container End Seal Angle Analysis

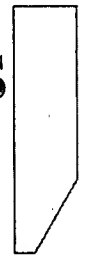
Case 1 – 120 deg

½ bag profile

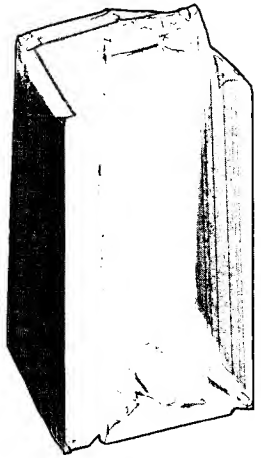


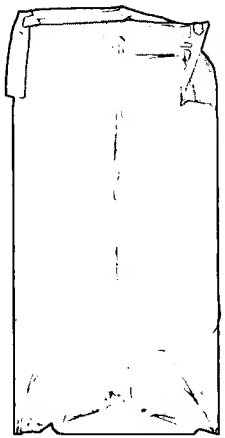
Container End Seal Angle Analysis

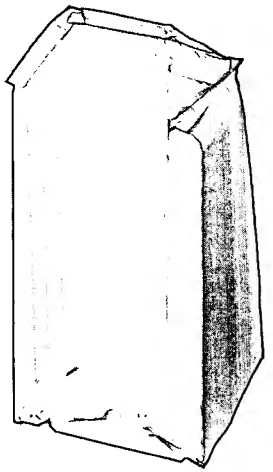
Case 1 – 150 deg

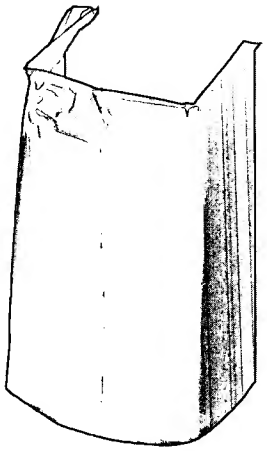


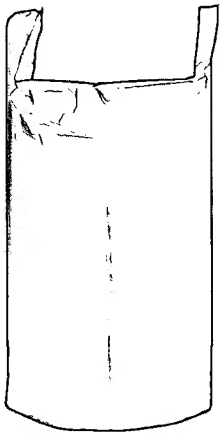
½ bag profile

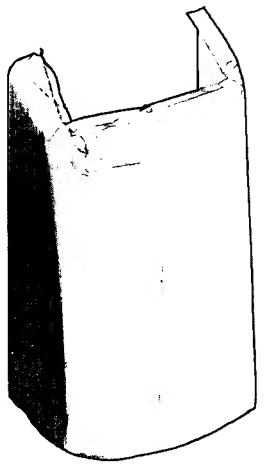








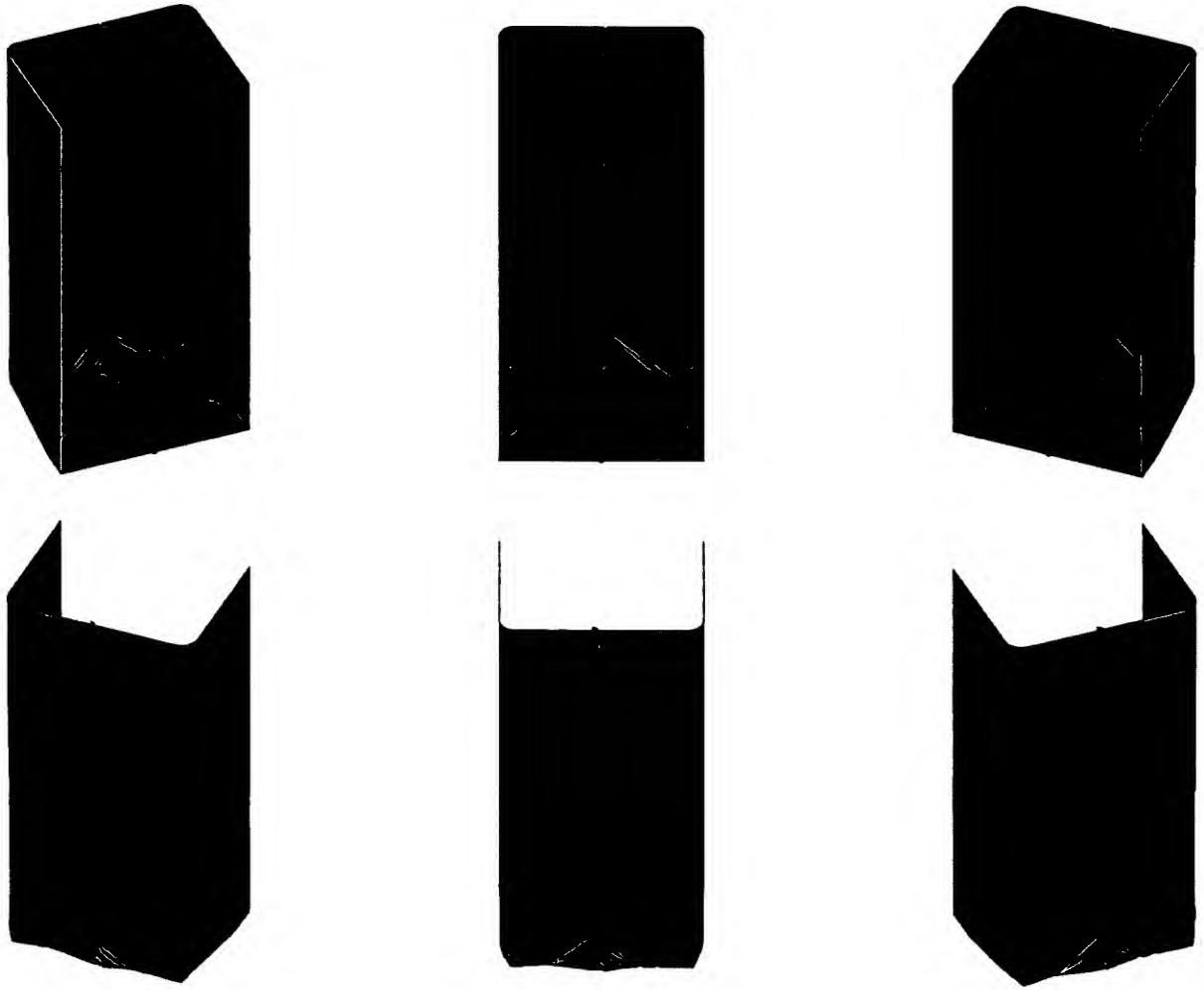




Container End Seal Angle Analysis

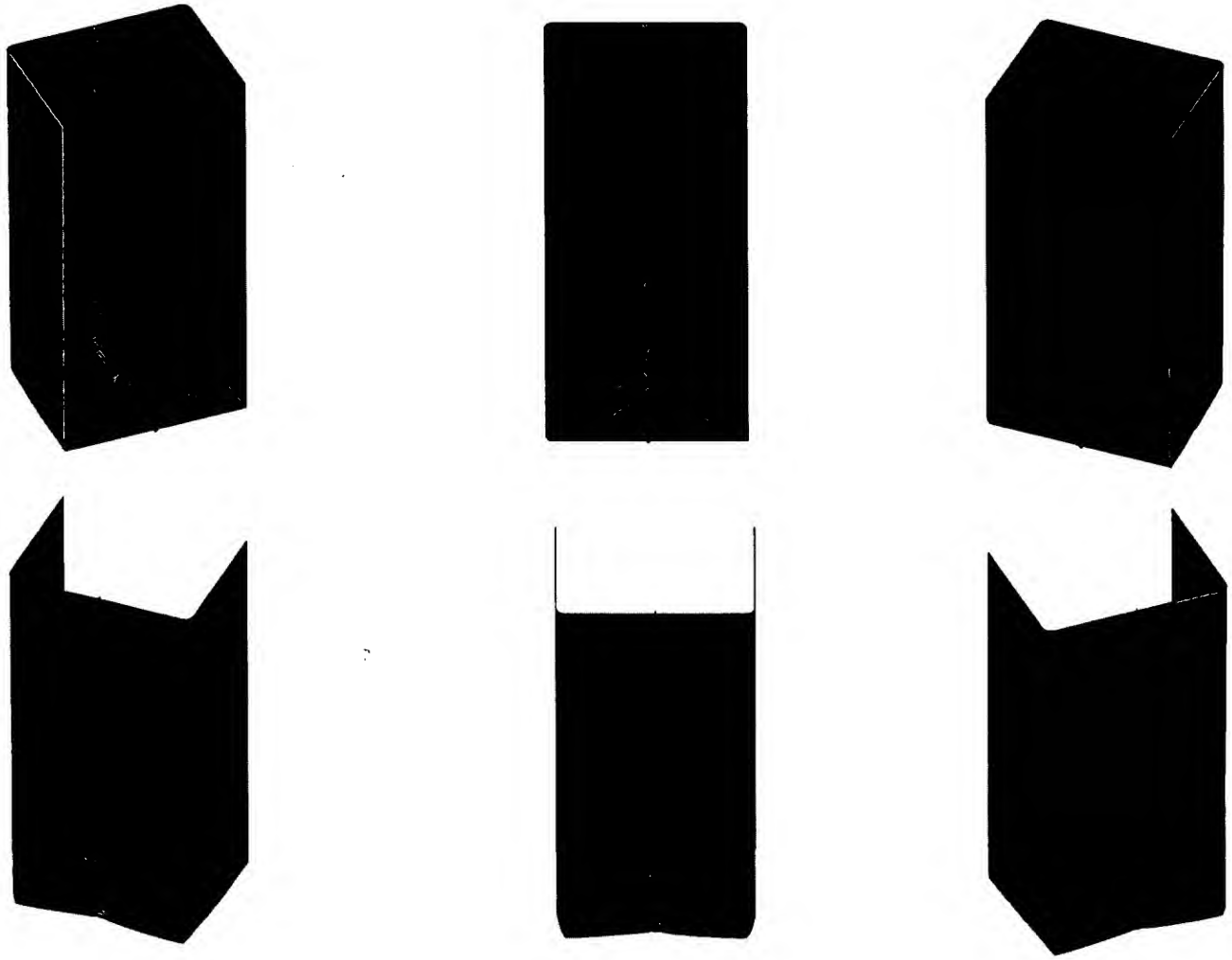
Case 1 – 138 deg

½ bag profile



Container End Seal Angle Analysis

Case 1– 135.01 deg



½ bag profile